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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,242	08/17/2000	Tomas Andrysek	UD&LP049	7359

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	14

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/642,242	ANDRYSEK ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1,3-24,26,28,30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,25,27,29,31,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to the directives of paper No. 13 (filed 10/29/02), claims 2, 25, 27, 29, 31 have been amended, and claims 33-34 added. Claims 1-34 remain pending. Claims 2, 25, 27, 29, 31, 33, 34 are examined in this Office action; claims 1, 3-24, 26, 28, 30, 32 remain withdrawn from consideration.

Applicants' arguments filed 10/29/02 have been considered and found persuasive in part.

*

Applicants are reminded of the preferred arrangement of the specification.

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

A figure legend is required. The following section heading should be supplied just before the figure legend:

BRIEF DESCRIPTION OF THE DRAWINGS.

Preferably, the "BRIEF DESCRIPTION OF THE DRAWINGS" section should precede the

"DETAILED DESCRIPTION OF THE INVENTION" section.

In addition, the abstract is objected to. The abstract should reflect the claimed subject matter, which is currently not the case. Additionally, in formulas 1 and 2 of the current abstract, an uppercase "N" is used, but only a lowercase "n" is defined. Also, the abstract should be no more than about 2/3 of a page.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 25, 27, 29, 31, 33, 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 recites (last two lines) that upon dilution with any amount of water, a dispersion is formed in which the mean size of particles is within the range of 0.2 - 500 μm. However, it does not appear that there is descriptive support for this. On page 8, line 1+, reference is made to the range of 0.2 - 500 μm. However, it is stated that particles within this size range are obtained only if the composition is combined with a specific

amount of an "aqueous phase". This passage does not say that, e.g., by adding water in the amount of 1 part-per-billion, that particles of any particular description are obtained. On page 18 (last two lines) reference is again made to the range of 0.2 - 500 μm. However, this is referring to a composition which contains both ethyl and oleyl alcohol, neither of which is suggested or required by the elected claims.

Applicants are requested to point out the passage that meets both of the following requirements: (a) the range of 0.2 - 500 μm is obtained regardless of the amount of water used, and (b) the range of 0.2 - 500 μm is obtained when no alcohol is present.

*

Claims 2, 25, 27, 29, 31, 33, 34 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 2 recites that the "average quantity of reacted ethylene oxide... ranges between 50 and 150 mols". However, this is not particularly meaningful as such. Suppose that one carries out the reaction on a 1 gram scale? In one gram, only about 23 millimoles of ethylene oxide would be present.

- Claim 2 recites that the ratio between components (b) and (d) is within the range of 0.1:1 and 10:1. However, this renders the claim indefinite as to whether this is determined on the basis of weight or moles.

- Claim 27 permits a taxane to be present, which is neither required nor suggested by claim 2. It is suggested that claim 27 be cast in independent form. Alternatively, claim 2 could be amended to recite that taxane is optionally present.

- Claim 31 recites "a dosage form containing a formulation according to claim 2".

Implicitly, this claim mandates that, in addition to the various components permitted by claim 2, at least one other component must be present. However, what the nature of this new component might be is not indicated by the claim. One or more of the following could be used:

A gelatin capsule which contains a formulation according to claim 2.

A gelatin capsule which contains a formulation according to claim 2 in combination with a pharmaceutically acceptable carrier.

A composition comprising a formulation according to claim 2 in combination with a pharmaceutically acceptable carrier.

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 2, 25, 27, 29, 31, 33, 34 are rejected under 35 U.S.C. §103 as being

unpatentable over Stuchlik (WO 98/10747).

As indicated previously, Stuchlik discloses (e.g., page 4) compositions comprising cyclosporin and polyglycerol esters. The reference does not disclose the specific ratios of components. However, it is within the capability of the ordinarilly skilled drug formulation specialist to vary dosages in order to achieve a target pharmacokinetic objective.

In response to the foregoing, applicants have amended claim 2 to recite that if the claimed formulation (call it the "first" composition) is combined with water, a "second" composition is thereby obtained, wherein the properties of the "second" composition could not necessarily have been predicted in advance of experimentation. The first point to be made is that applicants are not claiming this "second" composition. The second point is that applicants are not claiming a method of preparing a "dispersion of non-spherical polymorpous gel particles having a dimension of 0.2 -500 μm". Rather, applicants are claiming a mixture which is not necessarily a dispersion, and which does not necessarily contain gel particles, spherical or otherwise. If applicants were claiming a mixture which contains a "dispersion of non-spherical polymorpous gel particles having a dimension of 0.2 -500 μm", then perhaps there would be novelty. But such an embodiment is not directly at issue. An analogy might be helpful here. Consider the following claim:

100. A composition comprising aspirin in combination with a pharmaceutically acceptable carrier.

Clearly, there are many references which would anticipate such a claim. Next, suppose that the applicant asserted that by formulating the aspirin in a particular amount, hair growth of the recipient could be stimulated. This hypothetical applicant submits the following claims:

101. A composition comprising a pharmaceutically acceptable carrier together with aspirin in an amount effective to stimulate hair growth.

102. The composition according to claim 101, wherein the amount of aspirin is 200 milligrams.

As it happens, this claim 101 would be obvious if a medical practioner had reason to select a dosage of 200 mg aspirin. Continuing with this example, suppose that applicant #2 submitted the following claim (claims 103-104), and applicant #4 submitted the following claims 105-106:

103. A composition comprising a pharmaceutically acceptable carrier together with aspirin in an amount effective to stimulate production of growth hormone.

104. The composition according to claim 101, wherein the amount of aspirin is 210 milligrams.

105. A composition comprising a pharmaceutically acceptable carrier together with aspirin in an amount effective to reduce blood pressure.

106. The composition according to claim 101, wherein the amount of aspirin is 220 milligrams.

Is it applicants view that claims 103-104 are patentable over claims 101-102, or that claims 105-106 are patentable over claims 103-104...? The point is that in selecting an amount of the aspirin to use, the medical practioner need not have the same motivation for selecting a given dosage as that of a given applicant, in order for obviousness to accrue.

Turning back to the claimed composition, the drug formulation specialist of ordinary skill need not have the same motivation for selecting a given amount of component (b) or (d) as applicants. Upon selecting the amounts falling within the scope of the instant claims, the requisite particle sizes will inevitably be obtained in the event that the drug formulation specialist makes the decision to combine the formulation with water.

Furthermore, it appears that the only composition tested for formation of the "dispersion of non-spherical polymorpous gel particles having a dimension of 0.2 -500 μm" contains both ethyl and oleyl alcohols, neither of which is suggested or required by the instant claims. Accordingly, it may well be the case that no such particles are formed in the absence of these alcohols.

Furthermore, even if applicants' arguments regarding claim 2 were correct, the same would not necessarily be true about claim 31 or 33. These claims permit other components to be present in the mixture, and neither of these claims (31 or 33) require that upon combining the "dosage form" with water, a "dispersion of non-spherical

polymorpous gel particles having a dimension of 0.2 -500 μm" is obtained.

The rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800